PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.:	10/621,972	Confirmation No.: 2230
Applicant :	Ross S. Tsugita	
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TC/A.U. :	3734	
Examiner :	Blatt, Eric D.	
Title :	FILTER FLUSH SYSTEM AND METHODS OF USE	
Docket No. :	1001.1421103	
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REPLY BRIEF

Mail Stop Appeal Brief - Patents
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By _____
JoAnn Lindman

Dear Sirs:

Pursuant to 37 C.F.R. § 41.41, Appellant hereby submits this Reply Brief in furtherance of the Notice of Appeal filed on March 15, 2010, the Notice of Panel Decision from Pre-Appeal Review dated mailed May 21, 2010, the Appeal Brief filed on July 14, 2010, and the Examiner's Answer mailed October 15, 2010. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $540 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

ARGUMENT

A. With regard to the Examiner's repeated position in the Examiner's Answer that the originally filed specification mentions an infusion port only in reference to element 54 in Fig. 3b and element 70 in Fig. 5, both of which are located near the distal

end of catheter, Appellant notes that this rejection has been discussed in detail in the Appeal Brief. The Examiner clearly errs in asserting that it is necessary to disclose in detail what is well known to one of ordinary skill in the art.

> What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. >See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005)("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge.... As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.").< If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient"). (MPEP 2163. II., 3., (a).)

The term "infusion port" is used in the art to indicate a port at the proximal end of a catheter through which the medications, parenteral nutrition, or IV solutions to be infused are introduced from outside the body. Such ports are known to be used to introduce fluids or medications to be delivered intravenously into the proximal end portion of a catheter and may be used with or without implantation of a supplying reservoir. This well known usage is consistent with the illustrated use of an infusion lumen and proximal end port in view of the specification as interpreted by one of ordinary skill in the art.

"In still another embodiment, the guiding catheter includes an infusion port proximal to the occlusion balloon. The port communicates with an infusion lumen in the catheter and is adapted for infusion of fluid or pharmaceutical agents. Using the infusion port, the dosage of pharmaceutical agent required to achieve local effect can be reduced compared to administration by systemic route." (Page 7, lines 11-15.)

Examples of fluid introduction ports at the proximal ends of catheters, identified as infusion ports, are common in the art and may be found for example in U.S. Patent No. 5,624,414, "Needleless straight infusion port".

Paragraph [0014] of the published application (page 7, lines 11-13 of the application as filed, cited below by the Examiner, states directly that there is "an infusion

port proximal to the occlusion balloon" which is sufficient disclosure to encompass the commonly employed practice of locating an infusion port at the proximal end of the guide catheter or "within the proximal end region and proximal the balloon" as recited in dependent claim 63.

Appellant respectfully requests that the rejection of claim 63 under 35 U.S.C. 112 be overruled.

If for any reason this argument and the argument presented in the Appeal Brief are deemed insufficient, points raised earlier by the Examiner will be addressed as follows:

Originally filed claim 1 recites "a guiding catheter having a proximal end, a distal end, and a lumen therebetween". Original claims 12 and 27 recite "wherein the guiding catheter includes an infusion port proximal to the occlusion balloon". Original claim 28, which depends from claim 27, recites "infusing fluid medium or blood through the infusion port. Figs. 2C, 3C, and 4C each illustrate infusing fluid from the proximal region of guide catheter 30 through infusion lumen 33 of guide catheter 30 where it exits through distal port 35.

As acknowledged by the Examiner's Answer, the embodiment of Fig. 5 illustrates an embodiment in which catheter 30 includes "infusion port 70, which is proximal to occlusion balloon 40 and communicates with lumen 33 of guiding catheter 30". (See page 18, lines 6-8.) The balloon 40 is recited as located in the distal end region of the guide catheter; however the specification does not explicitly define a proximal end region. Nothing in the comprising language of claim 53 or the language of dependent claim 63 precludes the presence of an additional infusion port 70 proximate the balloon so long as the remaining claim limitations also are met. Any configurations of the catheter of Fig. 5 which stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded are encompassed by claim 53 if other limitations such as "a fluid lumen connecting the proximal end region and the distal end region", "a balloon coupled to the distal end region of the first catheter shaft", "first catheter shaft [which] defines a perfusion lumen configured for the passage of perfusing fluid supplied at the proximal

end region therethrough so as to flush embolic debris into the filter", "a stent disposed adjacent the second catheter shaft", and the like are met. Such configurations may include unspecified valves, seals, or other internal obstructions which are configured to stop fluid from entering port 70 and exiting through the distal end of the catheter of claim 53.

With regard to the term "proximal end region" found in the disputed claim 63, Appellant directs attention to page 3 of the final Office Action in which the Examiner asserts, with reference to the catheter of Patel, that:

"The guiding catheter taught by Patel has an end region extending from port 27 to the distal tip of the catheter. The portion of this end region that lies proximal to the balloon is considered a proximal end region"

Accordingly the Examiner's interpretation of "a proximal end region" of Patel, as applied to the disclosure of the pending application, results in port 70 of Fig. 5 of the pending application being located in "a proximal end region" of catheter 30 as recited in claim 63 and thus provides the necessary disclosure. If not port 70, another port of the plurality of proximal infusion ports described at page 18, lines 10-12 will serve to provide the necessary disclosure of an infusion port within the proximal end region and proximal of the balloon.

The term "infusion port" is used in the art to indicate a port at the proximal end of a catheter through which the medications, parenteral nutrition, or IV solutions to be infused are introduced. Such ports are known to be necessary to introduce fluids or medications to be delivered intraveneously into the proximal portion of the catheter and may be used with or without implantation of a supplying reservoir. This well known usage is consistent with the illustrated use of a fluid lumen and proximal end port as the claim would be interpreted by one of ordinary skill in the art in view of the specification. Examples of proximal fluid introduction ports which are identified as infusion ports are common in the art and may be found for example in U.S. Patent No. 5,624,414, "Needleless Straight Infusion Port".

Common usage encompasses the use of "infusion port" to designate a port through which fluids to be infused into a vessel are introduced into a fluid lumen of a catheter and also to designate the port through which the fluids within a catheter are

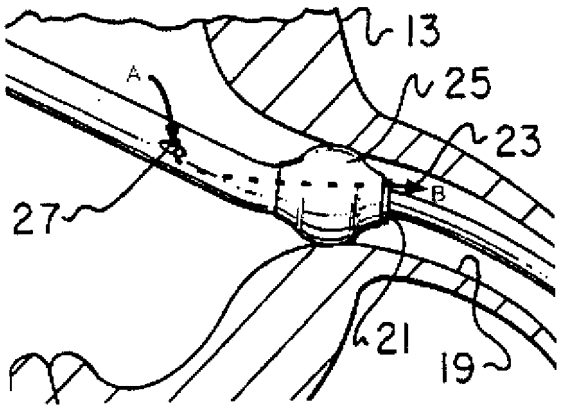
infused into the vessel. Accordingly the proximal end of a fluid lumen would be understood by one of ordinary skill in the art to provide an infusion port which is present in the proximal end region of a catheter having a fluid lumen connected to a distal infusion port. This would be the case whether the proximal portion of the fluid lumen is open external to the body as shown in Figs. 1B, 2A-C, 3A-C, 4A-C, and 5 or closed as by a septum, Luer connector, or valve, each of which is commonly employed practice.

Appellant respectfully requests that the rejection of claim 63 be overruled.

B. With regard to the Examiner's positions with respect to Gray in view of Patel, the Examiner clearly errs in asserting that the recited blood flow is restricted by the claim language to flows past a toroidal balloon which occur by remaining exclusively outside of the catheter and, for example, by flowing around the outer diameter of the balloon of Patel (as when the balloon is not sufficiently inflated or when the balloon is not seated in the ostium). The pending claims in question recite:

"wherein the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded"

Contrary to the Examiner's interpretation, nothing in the claims specifies that the fluid path to be stopped is around the outermost extent of the balloon thereby excluding the path taken by fluid flowing from point "A" to point "B" in the figure below. Appellants submit, with reference to the modified detail of Fig. 2 of Patel reproduced below, that blood in the region designated "A", which is both outside of guiding catheter shaft 11 and proximal of balloon 25, will enter side hole 27 of guide catheter 11 as taught by Patel, at col. 1, lines 47-56, and will flow distally past the inflated balloon 25 (by flowing through the central hole of the torus formed by the balloon), and will flow out the tip 23, the distal region of catheter 11, to the region designated "B" which lies distally past the distal region of the shaft of catheter 11.



Patel explicitly describes this path and flow several times as discussed in detail in the Appeal Brief. The Examiner's arguments regarding the path taken by that flow are immaterial to the plain language of the claims which only recite that the device be configured such that the recited flow from point "A" to point "B" is stopped.

The Examiner acknowledges that "Gray fails to disclose a first shaft (claim 53) or outer catheter shaft (claim 68) with a balloon coupled thereto" and relies upon Patel to teach a guiding catheter 11 with a balloon 25 coupled thereto. As illustrated above, and as described in detail by Patel:

> "The side hole 27 passes through the guiding catheter 11 to allow blood to flow from the aorta 13, through the side hole 27, and out the tip 21 of the guiding catheter 11." (Column 2, lines 20-23.)

Accordingly, the guide catheter 11 of Patel does not stop fluid outside the guide catheter 11and proximal of balloon 25 from flowing out the tip 21 and so flowing distally past the distal region of catheter 11 when the balloon 25 is expanded.

It should be noted that optional port 70 of Fig. 5, as discussed above in the context of the Examiner's Answer, is not necessarily present as may be seen in Figs. 2C, 3C, and 4C and so does not necessarily provide a bypass analogous to that of Patel. Even were the port 70 to be present, inflow through port 70, required for bypass from the outside proximal region when the balloon is inflated, does not necessarily (inherently) occur, for example, when the catheter is configured such that the pressure within the lumen is greater than the pressure outside the shaft in the vicinity of port 70 as would be the case when fluid is being delivered through the lumen. In addition, other structure (not shown),

such as elements associated with the perfusion lumen (see claim 53) of the first catheter shaft, may be present in various configurations of the catheter, which structures would prevent blood from entering the catheter, but which would not prevent infusion of fluids outward into the vessel through infusion port 70.

> infusion: "(medicine) the passive introduction of a substance (a fluid or drug or electrolyte) into a vein or between tissues"
> (http://www.onelook.com/, summarizing 71 dictionaries, November 4, 2010)

The "temporary vascular filter guide wire" of Gray does not advance a filter and/or dilating catheter through a first or outer guiding catheter and over a guidewire as taught by Patel and thus would not appear to encounter the potential problem of "forcing the guiding catheter out of the coronary lumen" which Patel addresses by providing a non-occlusive anchoring balloon at the distal end of the guide catheter. In the absence of the resulting reactive forces which may give rise to the described ejection problem, or even of an outer guiding catheter upon which said forces might act, the apparatus of Gray does not have a problem which would be solved by the Examiner's proposed combination with Patel. The problem solved by Patel, which is said to provide motivation for the combination of Gray and Patel as proposed by the Examiner, does not exist until the outer catheter of Patel is added, unnecessarily, to the functionally sufficient filter guidewire of Gray.

Appellant respectfully requests that the rejections of claims 53-58, 60-65, and 68-71 be overruled.

C. With regard to the Examiner's further argument that the proximal end infusion ports of claims 63 and 64 must necessarily be limited to those of Figs. 3B and 5, it should be noted that port 54 of Fig. 3B is not located in the first catheter shaft 30 as recited in claim 53 from which claims 63 and 64 depend, but rather is located on a second catheter shaft (angioplasty catheter 50). Port 70 of Fig. 5 has been discussed above and in the Appeal Brief. Cited paragraph [0014] of the published application states:

> "In still another embodiment, the guiding catheter includes an infusion port proximal to the occlusion balloon. The port communicates with an infusion lumen in the catheter and is adapted for infusion of fluid or pharmaceutical agents. Using the infusion port, the dosage of

pharmaceutical agent required to achieve local effect can be reduced compared to administration by systemic route." (Page 7, lines 11-15.)

There is no indication that the port in question corresponds to either port 54 of the second catheter (Fig. 3B) or to port 70 of Fig. 5. Instead, the text states that there is an infusion port proximal to the balloon without explicitly specifying the location. Cited paragraph [0030] of the published application identifies Fig. 5 as depicting an embodiment of the guiding catheter "having an infusion port proximal to the occlusion balloon without identifying that port as port 70. Cited paragraph [0041] of the published application describes the angioplasty catheter and not the guide catheter. Cited paragraph [0047] of the published application describes the embodiment Fig. 5 which is discussed in detail in this Reply and in the Appeal Brief.

In referring to Appellant's response to the rejections of claims 63 and 64 as presented in the responses of June 2009 and December 2009, the Examiner fails to acknowledge that those rejections were explicitly addressed at page 9, lines 19-24 and at page 15, lines 15-17 respectively. The Examiner has clearly erred in characterizing Appellant's argument with regard to Fig. 5 and claim 53 as "explicitly stating that the embodiment shown in Fig. 5 does not fall within the scope of claim 53. That argument, reproduced here for convenience was:

> 'In the Advisory Action, the Examiner states:
>
> "Clearly Applicant must regard these features to be compatible with one another or these features would not be claimed together."
>
> Appellant responds that the features in question are <u>not</u> claimed together. Port 70 of the embodiment of Fig. 5, *if operated in the manner taught by Patel*, would not be encompassed by either claim 53 or claim 68 for the simple reason that in that mode of operation the system would not be configured to stop flow in the manner recited in the claims. Other modes of operation would create differential pressures which would prevent port 70 from acting as an infusion port.'
>
> (Italic emphasis added.)

The argument above has been mischaracterized by omitting the effect of the phrase emphasized above. When "the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded" as recited in claim 53, the device of Fig 5 is encompassed within the scope of claim 53 and the port 70 of Fig. 5 does not function as the proximal end infusion port of claim 63. It is not inherent that port 70 must allow fluid flow to enter through the port as well as to exit distal of the distal region of the shaft. If a configuration exists in which the flow in question is not stopped, it is not encompassed by independent claim 53. The perfusing flow of claim 53 may be supplied through a perfusion lumen also recited in claim 53.

D. With regard to the Examiner's argument at page 10 of the Examiner's Answer, Appellant respectfully notes that the earlier presented argument that the balloon of Patel is not occlusive is explicitly acknowledged by the Examiner's quotation of col. 2, lines 65-68 which states, in part, "Blood flow is thus not restricted by the inflated balloon 25 on the guiding catheter 11." (Emphasis added.) The Examiner's position rests upon an incorrect assumption that Patel discloses an embodiment in which side hole 27 is not present. Patel repeatedly states that blood does flow in through side hole 27 as detailed in the Appeal Brief and elsewhere. Appellant has been unable to identify the Examiner's postulated embodiment of the apparatus of Patel which does not include side hole 27 within the disclosure of Patel.

Were the side hole 27 of Patel to be omitted, balloon 25 would restrict blood flow thereby altering the operating principle of the catheter of Patel and rendering the catheter unsatisfactory for anchoring the catheter in the coronary artery while maintaining a bypass blood flow in said coronary artery as the filter and stent system of Gray is advanced and deployed therethrough in the proposed combination of Gray and Patel.

E. With regard to The Examiner's comments regarding a putative motivation to combine Gray and Patel, Appellant notes that the balloon of Patel is said to overcome a problem which can only arise when a guiding catheter is employed with a dilating catheter such as that of Gray. The problem, described at col. 1, lines 36-52 of Patel,

relates to potential expulsion of the guiding catheter by a reactionary force generated by the dilating catheter. Gray does not employ a guiding catheter and thus does not experience the problem which the Examiner purports to solve by adding a guiding catheter. Thus the problem solved by the addition of the guiding catheter of Patel occurs in Gray only when a guiding catheter, such as that of Patel, is added. The Examiner has proposed a combination of references which creates the problem to be solved by the combination and one of ordinary skill in the art would not be motivated to create a problem where none existed.

The Examiner further asserts, with no apparent support in Patel or sufficient supporting rationale, that the addition of a guiding catheter of Patel "would improve the versatility and accuracy of the Gray system". Neither advantage has been found in the teaching of Patel. Instead, the guiding catheter of Patel appears to be highly, if not entirely, specific to the coronary artery and thus would reduce the versatility of the system of Gray.

For at least the above reasons, as well as others presented in the Appeal Brief, Gray in view of Patel does not teach all the claim limitations, as is required to establish a *prima facie* case of obviousness, and the Examiner does not appear to have considered all words of the claims in rejecting independent claims 53 and 68. Further, the Examiner does not appear to have provided a motivation for one of ordinary skill in the art to modify Gray by the addition of the guide catheter of Patel. Appellant respectfully requests that the rejection of independent claims 53 and 68 be overruled as well as the rejections of claims 54-58, 60-65, and 69-71 which depend therefrom. Further claims 59, 66, 67, and 78, which also depend from nonobvious independent claims 53 and 68 respectively, are also believed to be nonobvious for the reason that the addition of the disclosure of Dubrul does not overcome the deficiencies of Gray and Patel as applied to claims 53 and 68. Appellant respectfully requests that the rejections be overruled.

F. With regard to claims 56-58, as noted in the response of December 2009 at page 10:

"Applicant does not traverse the assertion that self-expanding stents are known in the art, only the assertion that the combination of Gray and Patel either teaches such a

self-expanding stent or that the combination would be suitable to deliver a self-expanding stent to an appropriate location within the stenosed vessel given the structures and operating principles associated with the two references."

The Examiner has repeated the assertion that a self-expanding stent is known in the art and that such a stent could have been delivered from a sheath not present in Gray; there is no such sheath in the disclosure of Gray and the outer catheter of Patel stops well short of the stenosis 31 of Patel and so would not appear to be suited to serve as the sheath which should be deposited by the balloon 33 as shown in Fig. 2. Thus, nowhere does Patel appear to remedy the shortcomings of Gray with respect to the self-expanding stent and the combination does not appear to be capable of delivering such a stent to the stenosis.

G. CONCLUSION.

For the reasons stated above, claim 63 was improperly rejected under 35 U.S.C. 112, first paragraph; the rejection of claim 78 under 35 U.S.C. 112, second paragraph is moot in view of the amendment of that claim; claims 53-58, 60-65, and 68-71 are nonobvious over Gray in view of Patel; claims 59, 66, 67, and 78 are nonobvious over Gray in view of Patel and Dubrul; claims 79 and 80 appear to have been improperly rejected; claim 81 is not present in the pending claims; and the Examiner's rejections of claims 53-71 and 78-80 under 35 U.S.C § 103 should be overruled.

Respectfully submitted,

Date: Dec. 14, 2010

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